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July 12, 2000

Ms. Kathy Eberhart
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 North
Rockville, Maryland 20852-1448
HFM 42

Dear Ms. Eberhart:

As an orthopaedic surgeon who has treated a number of trauma patients and done a number of reconstructive procedures requiring bone grafts from the bone bank, I would strongly urge the FDA not to choose to regulate allograft bone, tendon or connective tissues as devices.

First of all, they have been used safely for a number of years with care to preserve the tissue in a similar fashion to the way the blood banks preserve blood cells and plasma. There certainly have been some tragedies, as there have been in the blood bank, but the risk in recent years has been minuscule and the benefit has been substantial when bone grafts can be taken from the tibia of one person and used to reinforce the deficient femur in another person who is having revision of a hip replacement. Allograft bone is also extensively used in spinal surgery. If there are complex regulations, it is very reasonable to believe that the price will significantly increase and patient care will suffer.

Finally, as blood is clearly a tissue and is currently not classified as a device, I believe it is reasonable to continue to allow tissue grafts without excessive new regulation.

Sincerely,

John W. Lamb, M.D.

JWL/ah

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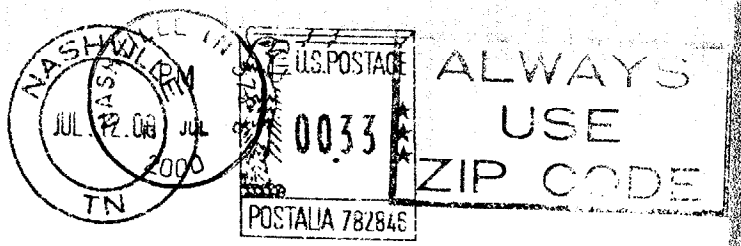

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